

Attorney Docket No.: **UT-0030**
Inventors: **Rao et al.**
Serial No.: **09/736,728**
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REMARKS

Claims 13-19 and 49 are pending in the instant application. Claims 13-19 and 49 have been rejected. Claims 13 and 49 have been amended. Support for these amendments is provided in the specification at page 5, lines 8 through 15, page 15, line 25, through page 16, line 12, page 23, line 26, through page 24, line 3, Example 1 at pages 17-20, Example 5 at pages 27 through 30, Example 6 at pages 30 through 32, and page 33, lines 1 through 15. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 13-19 and 49 under 35 U.S.C. § 102(e)

The rejection of claims 13-19 and 49 under 35 U.S.C. § 102(e) as being anticipated by Jat et al. (U.S. Patent 5,688,692) has been maintained. The Examiner suggests that Jat, at col. 25, lines 3-10, teaches selection of A2B5 expressing cells and obtaining glial cells as claimed. Further, the Examiner suggests that Jat et al. teach a method of obtaining and propagating a population of mammalian/E18 embryonic rat CNS glial precursor cells that are also differentiated into non-process bearing A2B5-GFAP+ astrocytes and A2B5+ oligodendrocytes in the presence of

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factors, PDGF, bFGF (i.e. col. 25 as it relates to claims 13-14, 18-19& 49), as well as in the presence of the factor, purified cortical astrocyte conditioned medium, which contains 10% fetal calf serum (i.e. col. 23, lines 47-54; as it relates to claims 14&15) that inherently also contains thyroid hormone; absent evidence to the contrary (e.g. col. 25, as it relates to claims 18-19). The Examiner further suggests that Jat et al. disclose a method of differentiation of glial restricted precursors in the presence of bFGF and CNTF and that process bearing A2B5+GFAP+ astrocytes are reasonably produced in their method (i.e. col. 25, as it relates to claims 16-17, as claimed).

Applicants respectfully traverse this rejection.

As also taught at col. 25 of Jat et al., the culture of Jat et al. labeled with A2B5 monoclonal antibody "looked like the O-2A progenitors". See specifically lines 5-10 of col. 25. In contrast, in the methods of the present invention the glial restricted precursor cells are distinct from O-2A progenitors.

Accordingly, in an earnest effort to advance the prosecution of this case and to clarify distinctions between the instant

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invention and the teachings of Jat, Applicants have amended claims 13 and 49 to clarify that the glial restricted precursor cells are phenotypically distinct from O-2A progenitor cells. Specifically, Applicants have amended the claims to clarify that the glial restricted precursor cells of the present invention are immunonegative for PDGF- α and PDGF- β receptors. In contrast, O-2A progenitor cells are positive for both the PDGF- α and PDGF- β receptors. See specifically Table 4 and teachings at page 29, lines 12-16 of the specification where this distinguishing feature is explicitly set forth. Additional support for this amendment and these distinguishing features of the cells used in the present invention from the cells used by Jat et al. can be found throughout the specification, for example at page 5, lines 8 through 15, page 15, line 25, through page 16, line 12, page 23, line 26, through page 24, line 3, Example 5 at pages 27 through 30, Example 6 at pages 30 through 32, and page 33, lines 1 through 15. Thus, no new matter is added by this amendment.

Since Jat et al. does not teach a method for obtaining glial cells from glial restricted precursors which are phenotypically distinct from O-2A progenitor cells, in particular with regard to

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their expression of PDGF- α and PDGF- β receptors, this reference can not anticipate the claims as amended. It is therefore respectfully requested that this rejection under 35 U.S.C. § 102(e) be withdrawn.

II. Rejection of Claims 13-19 and 49 under 35 U.S.C. § 103(a)

Claims 13-19 and 49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jat (U.S. Patent 5,688,692) in view of Gard. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to initially obtain a pure homogeneous population of Jat's glial progenitor cells before differentiating these progenitor cells to various populations of glial cells, as disclosed by both Gard et al. and Jat et al. using Gard's method of immunopanning with Jat's A2B5 antibody.

Applicants respectfully traverse this rejection.

MPEP § 2143 states that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the

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reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. The cited combination does not meet these criteria.

As discussed in detail in Section I, *supra*, Jat et al. does not teach or suggest use of glial restricted precursor cells which express the A2B5 antigen and which are phenotypically distinct from O-2A progenitor cells, in particular with respect to expression of PDGF- α and PDGF- β receptors. Instead, Jat et al. teach at col. 25, lines 5-10, that their cultures "looked like O-2A progenitors".

Gard et al. teach a method for obtaining a mixed population of cells from postnatal rat brain, in particular the optic nerve of 4 day old rats, via immunoselection with Gd3 ganglioside, O4 and galactocerebroside (GalC) antibodies. Thus, Gard et al. also fails to teach or suggest use of glial restricted precursor cells which express the A2B5 antigen and which are phenotypically distinct from O-2A progenitor cells.

Accordingly, in an earnest effort to clearly distinguish the present invention from the cited references, Applicants have

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amended the claims to clarify that the glial restricted precursor cells used are phenotypically distinct from O-2A progenitor cells in that they are immunonegative for PDGF- α and PDGF- β receptors. Support for this amendment can be found throughout the specification and in particular at page 5, lines 8 through 15, page 15, line 25, through page 16, line 12, page 23, line 26, through page 24, line 3, Example 5 at pages 27 through 30, Example 6 at pages 30 through 32, and page 33, lines 1 through 15.

Since neither Jat et al. nor Gard et al. teach or suggest use of cells with these characteristics, these references do not teach or suggest all the limitations of the claims. Thus, the cited combination of reference cannot render obvious the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

III. Rejection of Claims 13-19 and 49 under 35 U.S.C. § 112, second paragraph

Claims 13-19 and 49 have been rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential

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elements. In particular, the Examiner suggests that the claims must specify how "selecting cells expressing A2B5 antigen" is accomplished.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to state that the glial restricted precursor cells used in the present invention are isolated by positive immunoselection with an A2B5 antibody. Support for this amendment can be found in Example 1 at pages 17-20 and in particular at page 19, lines 4-7, and in Example 2, page 21, lines 11-13, wherein a source for the A2B5 antibody is provided.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested in light of these amendments.

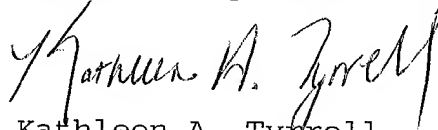
IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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Date: September 8, 2003

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